BIO-DESIGN INC A3686

OPERATING
INSTRUCTIONS

DEFIBRILLATOR ANALYZER

MODEL DA-2 AND MODEL DEM-2

BIO-DESIGN, INC.
Stoughton, Mass. 02072

A3L6

READ THIS INSTRUCTION MANUAL CAREFULLY BEFORE ATTEMPTING TO USE INSTRUMENT.

WARNING

THIS INSTRUMENT IS TO BE USED ONLY BY QUALIFIED PERSONNEL.

DISCONNECT POWER PLUG FROM LINE VOLTAGE BEFORE SERVICING.

DANGER - EXPLOSION HAZARD - DO NOT USE THIS INSTRUMENT IN THE PRESENCE OF FLAMMABLE ANESTHETICS.

CAUTION - DO NOT PERFORM TESTS IN THE PRESENCE OF CARDIAC CATHETERIZED PATIENTS.

LIMITED WARRANTY

Bio-Design, Inc. warrants this instrument to be free from defects in materials and workmanship. This warranty is effective for one year from the date of delivery to the original purchaser. We will repair or replace products, except for batteries, fuses, and test leads which prove to be defective within the warranty period. Defects arising from misuse or abuse of the instrument will be repaired or replaced at cost. No other warranty is expressed or implied. Bio-Design, Inc. is not liable for consequential damages.

SERVICE

When service is required, write, wire or phone Bio-Design, Inc. Depending on the nature of the defect, every effort will be made to ship a replacement part or instrument immediately. If it is necessary to return the instrument to the factory, pack carefully and securely, preferably in the original carton, and return it to Bio-Design, Inc., with shipping charges prepaid. Do not return products to Bio-Design, Inc. without prior consent.

BIO-DESIGN, INC.
Stoughton, Massachusetts 02072
(617) 344-8600

Printed in U.S.A.
December 1980

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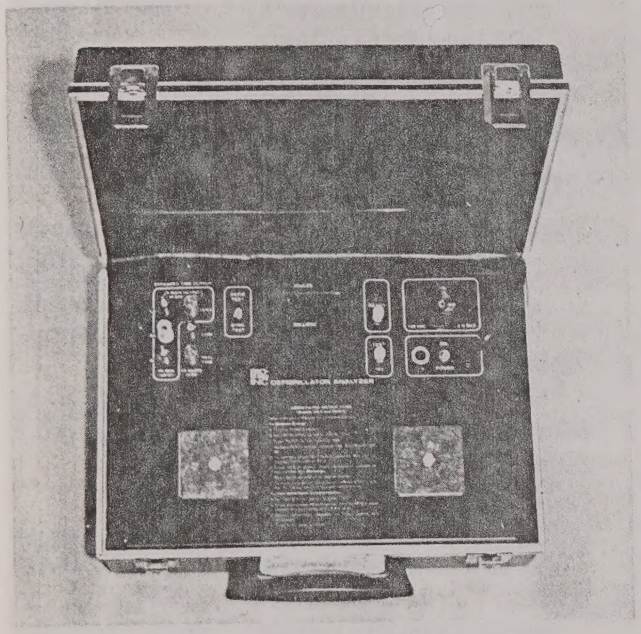


Defibrillator Analyzer, Model DA-2

1.0 INTRODUCTION

The Bio-Design Defibrillator Analyzer, Model DA-2, is designed to accurately and completely test the performance of capacitor-discharge or "DC" type defibrillators, one of the most important emergency instruments found in the hospital. The DA-2 is not to be used for testing "AC" defibrillators or damage may result.

The Model DA-2 has three functions: one is an Energy Level Meter which computes the energy delivered to a 50-ohm load resistor and displays it on a large, easy-to-read digital readout. The second function, called the Waveform Time Expander, is a waveform memory circuit that allows the actual defibrillator waveform to be written on an ordinary electrocardiograph for analysis and as a permanent record. The defibrillator output voltage and pulse duration can actually be measured directly from the ECG tracing. Figure 1 shows a typical defibrillator waveform recorded from the DA-2. Please note that the waveform may be upside down if the paddles are reversed as in Figure 2. The third function is a synchronizer test which measures and displays the time delay, in milliseconds, between an internally generated R-wave and a defibrillator discharge.

NOTE: The Model DEM-2, which contains only the Energy Meter and the synchronizer test, may be upgraded at any time to the Model DA-2 which includes the waveform memory. Please consult the factory. This instruction manual applies to both models. If you have model DEM-2 please disregard those sections of the manual which refer to the waveform memory.

2.0 SPECIFICATIONS

2.1 Energy Level Calculator

Range:	10-900 watt seconds (joules)
Accuracy	150 to 900 w-s: ±2% of reading ±1 digit. 40 to 150 w-s: ±4 digits 10 to 40 w-s: ±10% of reading ±1 digit
Display:	Three 7-segment digits, 11 mm (0.43 in.) high
Waveform Length:	Accepts waveforms up to 40 milliseconds in length.
Waveform Amplitude:	4000 volts maximum linear input

2.2 Waveform Memory (Not contained in Model DEM-2)

Range:	±4000 volts maximum linear input
Time Expansion Factor:	200 to 1
Frequency Response:	DC to 1000 hz (-3db)
ECG Waveform Readout:	At ECG paper speed of 25mm/sec, each 5 millimeter chart division corresponds to 1 millisecond. (Compensated for ECG time constant of 3.2 seconds.)
Expanded Time ECG Output:	3 jacks with adapters are provided for connecting 3 ECG electrodes in Lead 1 configuration (LA, RA, RL)
Scale Factor:	1 millivolt out per 1000 volts in
Output Impedance:	10,000 ohms (LA). RA and RL connected to chassis ground.
Expanded Time High-level Output:	Binding post to connect to an oscilloscope or recorder.
Scale Factor:	1 volt out per 1000 volts in
Output Impedance:	2000 ohms
Scale Factor Accuracy:	±3% of input amplitude; or ±40 volts—whichever is larger

2.3 Synchronizer Test

R-Wave Output	1 volt pulse at Expanded Time jack 1 mv pulse at LA jack 1 mv pulse at Input Plates, Rate = 60 BPM
Range:	5 msec to 999 msec
Accuracy:	± 1% of reading ± 1 digit

2.4 General

Input Load Resistor:	50 ohms ±1% (non-inductive)
Scope Output—Real Time:	Binding post to connect to an oscilloscope to view actual defibrillator pulse. Scale factor is 1 volt out per 1000 volts in.
Output Impedance:	3000 ohms
Power Requirements:	120 VAC, 0.1A, or 230 VAC .05 A, 50/60 hz
Line Voltage:	105-135 VAC, or 200-260 VAC
Circuit Breaker:	.1 amp
Size:	33 cmx23 cmx14 cm (13x9x5½in.)
Weight:	3.2 kg (7 lbs.)

120 VAC convenience receptacle rated at 5 amperes is provided for connecting ECG.

3.0 CONTROLS (See Figure 3)

3.1 Power Switch: Turns on AC power to DA-2 circuits.

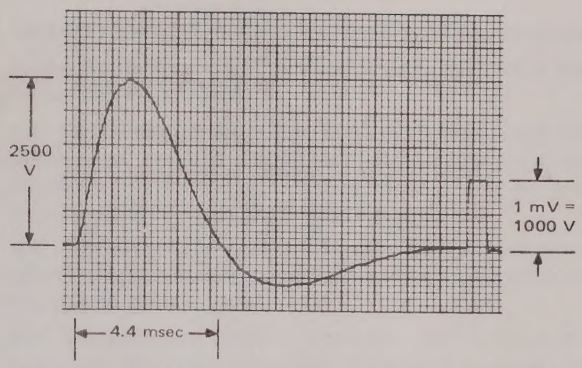


Figure 1. Typical defibrillator waveform recorded on ECG from DA-2 time-expanded output

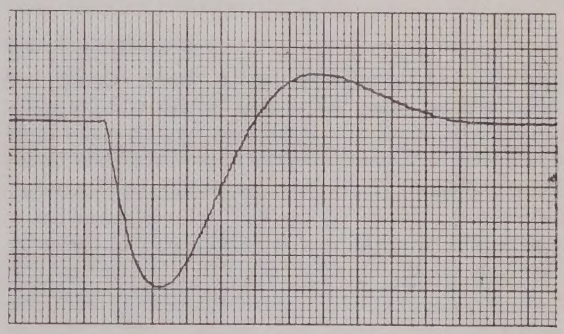


Figure 2. Upside-down waveform due to reversed defibrillator paddles

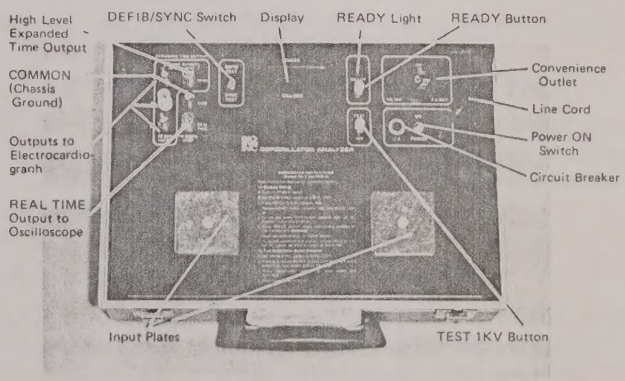


Figure 3. Controls, Inputs, Outputs and Indicators

3.2 READY Button: When depressed all seven segments of each display LED should light, displaying "888." When released display reads "000," READY light glows indicating all circuits are cleared and reset, and ready to receive an input.

3.3 TEST 1KV Button: Simulates 1 kilovolt (1000V) step at input. If depressed when READY light is on, a calibration number (between 775 and 825) will appear on the energy meter display, a 1 millivolt pulse will appear at the ECG output and a 1 volt pulse will appear at the scope output.

NOTE: The test number should remain within ±25 of the original number when the DA-2 is operating properly. If number deviates, see Warranty and Service page for instructions.

3.4 DEFIB/SYNC TEST Switch: In the DEFIB TEST position, the display reads defibrillator energy in JOULES, and the waveform appears at the Expanded Time Outputs. In the SYNC TEST position, the display reads synchronizer delay in MILLISECONDS and an interally-generated R-wave appears at the Expanded Time Outputs and at the Input Plates.

4.0 INPUTS AND OUTPUTS

4.1 Power Plug and Line Cord: Connects to 50/60 hz outlet of appropriate voltage. (120 VAC or 240 VAC as indicated on serial number label.)

4.2 Input Plates: Two nickel-plated brass plates to which the paddles of the defibrillator-under-test are applied. The discs are electrically-connected to the 50-ohm test resistor and through high voltage resistors to the input circuit.

NOTE: Right-hand disc is non-inverting input, left-hand disc is inverting input.

In the Synchronizer test, a 1 millivolt internally generated R-wave appears between the Input Plates.

4.3 Outputs to Electrocardiograph: Three jacks marked LA, RA, and RL to which the electrocardiograph patient cable is attached. The time-expanded output is provided at these terminals for recording the defibrillator waveform. The scale factor is 1 millivolt out per 1 kilovolt (1000 volts) in. The ECG is set to Lead 1, 25mm/sec.

In the Synchronizer test, a 1 millivolt internally generated R-wave appears at the LA output.

4.4 Expanded Time High-Level Output: Binding post which supplies a high-level expanded-time output (1 volt out per kilovolt in) for oscilloscope or recorder. Signal

appears between Expanded Time post and Common post.

In the Synchronizer test, a 1 volt R-wave appears at the Expanded Time Output.

4.5 Real Time Output: This binding post supplies the attentuated, buffered defibrillator pulse for viewing on an oscilloscope, if desired. Scale factor is 1 volt out per kilovolt in, referenced to Common post.

4.6 Common Terminal: This binding post is connected to chassis ground and serves as the reference terminal for the output signals.

4.7 Convenience Outlet: Provides AC voltage for electrocardiograph or recorder. Rated at 5 amperes. Do not connect the defibrillator-under-test to this outlet, as its current requirement may be too high for the outlet. Note: Outlet is live when DA-2 is plugged into AC source.

5.0 INDICATORS

5.1 READY Light: A light-emitting-diode which glows when READY button is pressed. Indicates that circuits have been cleared and reset, and ready to receive an input. The READY light will extinguish after a defibrillator pulse or TEST 1KV signal is applied. If a defibrillator pulse is applied when the READY light is *OFF*, it will not be accepted by the circuitry; a new indication of energy will *not* appear, and a new waveform will *not* be obtained.

5.2 Energy Display: Displays energy in joules delivered to built-in load resistor. Uses three 7-segment displays and red acrylic filter for high visibility. Range is 10 to 900 joules. When "READY" button is depressed, all seven segments of each display are energized displaying "888" and assuring that all segments are properly operating.

5.3 JOULES indicator is lit in the DEFIB TEST mode.

5.4 MILLISECONDS indicator is lit in the SYNC TEST mode.

6.0 OPERATING INSTRUCTIONS (DEFIB. TEST)

6.1 Connect DA-2 power plug to 50/60 hz outlet: See nameplate inside cover for proper operating voltage. **Connect only to three-wire outlet which has a properly-wired safety ground.**

6.2 Turn on POWER Switch

6.3 Set DEFIB/SYNC switch to DEFIB TEST.

6.4 Connect Electrocardiograph (ECG) to LA, RA, and RL Terminals of the DA-2: Turn on ECG and set to Lead 1 position. Set speed to 25mm/sec. (It is not necessary to run ECG paper drive at this time.)

6.5 If desired, an oscilloscope may be connected to DA-2 in order to observe actual defibrillator output pulse. Connect oscilloscope ground to COM terminal and oscilloscope probe to REAL TIME terminal.

6.6 Press READY Button: Digital display should read "888." This indicates that all segments of readout devices are working properly.

6.7 Release READY Button: READY light should be "on" indicating the DA-2 circuits are now ready to accept a defibrillator pulse.

6.8 Press "TEST 1KV" button: This simulates a 1000 volt pulse into the DA-2. The energy display will read 800 ±25. If the number deviates or if no number appears, see Warranty and Service page for instructions.

A one millivolt step will appear at the ECG output terminals. This corresponds to 1000 volts at the DA-2 input and may be used to calibrate the ECG. Run the ECG paper drive and adjust ECG sensitivity so that one millivolt equals 10 millimeters. The scale factor in the ECG chart will now be 1000 volts/cm or 100 volts/mm. See Figure 4 for typical ECG recording TEST 1KV signal.

6.9 Press and Release READY Button.

6.10 Set Defibrillator-Under-Test to Desired Energy Level.

6.11 Apply Paddles of defibrillator-under-test to DA-2 input discs. Press down firmly.

6.12 Discharge Defibrillator.

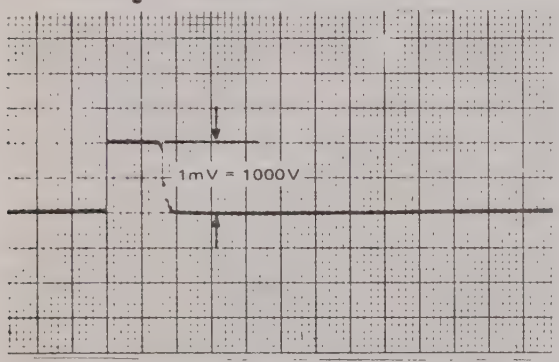


Figure 4. ECG recording DA-2 Calibrate Signal

6.13 Energy meter now displays the energy (in JOULES) delivered to the 50-ohm resistor built into the DA-2. Record energy on data sheet or on ECG chart paper. See Figure 5 for sample defibrillator waveform and data sheet.

6.14 Run the ECG for approximately ten seconds to record the output waveform of the defibrillator-under-test.

NOTE: The DA-2 output waveform repeats every 8 seconds until the READY button is pressed, (or until the AC power is turned off), at which time the waveform is deleted from the memory. Thus, the waveform may be recorded at any convenient time after the defibrillator is discharged and before the READY button is pressed.

6.15 Repeat steps 6.9 through 6.14 for several different settings. Record results on data sheet or on ECG chart paper.

Figure 5. Sample defibrillator test data sheet

DEFIBRILLATOR TEST DATA SHEET

Mfr. _____ Model _____ Serial No. _____

Tested by _____ Date _____ Date Next Test _____

	Ok	Need Repair
1. Visual: Line Cord	_____	_____
Power Plug	_____	_____
Paddles	_____	_____
Cable and connectors	_____	_____

2. Electrical: Grounding wire resistance _____ ohms
   Leakage current, chassis to ground -
   Polarity Normal _____ uA
   Polarity Reverse _____ uA
   Leakage current, paddles to ground -
   Polarity Normal _____ uA
   Polarity Reversed _____ uA
3. Operation: Charging time to maximum energy ___ sec.
4. Energy Output:

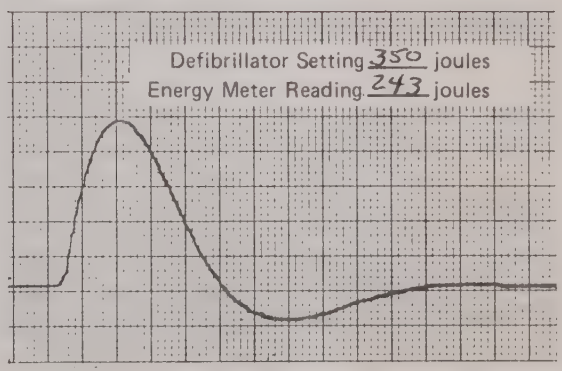
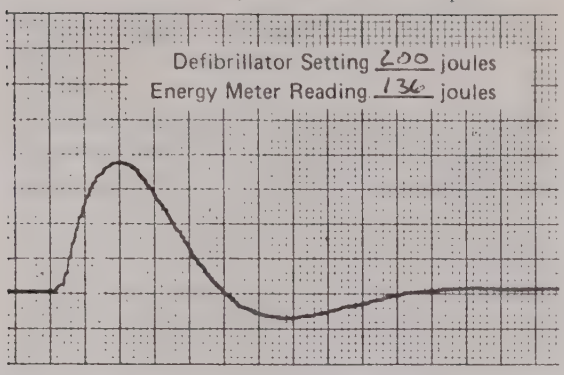
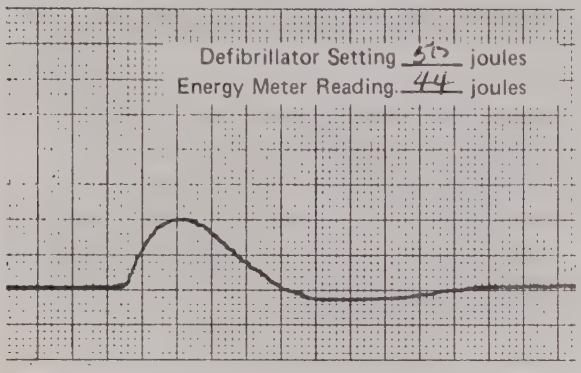


Figure 5. (cont.)





Output Waveform of 10th repeated discharge at maximum setting:

Defibrillator _____ joules

Energy Meter Reading _____ joules

Attach Waveform Here

7.0 TIPS IN TESTING DEFIBRILLATORS

7.1 Be sure that the DA-2 and the defibrillator-under-test are plugged into properly grounded AC outlets. If an ECG is used to record the defibrillator waveform, plug it into the convenience outlet on the DA-2 front panel.

7.2 Be sure that the "READY" light is on before discharging the defibrillator into the input discs.

7.3 Periodically press the "READY" and "TEST 1KV" button in sequence to assure proper operation of the DA-2 circuits.

7.4 If you discharge defibrillator-under-test into input discs and get no energy meter indication or no output waveform, follow these steps:

(a) Be sure power is applied to DA-2. Check circuit breaker. Check outlet for proper voltage.

(b) If ECG is not on, check ECG fuses.

(c) Press READY button, be sure READY light is on.

(d) Be sure that the energy meter of defibrillator indicates a charge.

(e) Be sure that the paddles are firmly applied to the input discs.

(f) Try again.

(g) If still no response, see Warranty and Service page for instructions.

8.0 RECORDING WAVEFORMS ON AN ELECTROCARDIOGRAPH

8.1 To achieve accurate ECG recordings of defibrillator waveforms using the Model DA-2 Defibrillator Analyzer, it is important that the AC coupling time constant of the ECG and the DA-2 be properly matched. The DA-2 ECG output circuit contains a network which compensates for a time-constant of 3.2 seconds, the value recommended by the American Heart Association Committee on Electrocardiography.[1] If the electrocardiograph used has a time-constant lower than 3.2 seconds, the recorded defibrillator waveform will contain some distortion appearing as slightly lower peak voltage, slightly larger undershoot, and shorter pulse duration.

Incorrect compensation of the ECG time constant can also be observed by recording the DA-2 "TEST 1KV" signal. Figure 6 shows tracings made on a correctly compensated ECG, while Figure 7 shows tracings made on an ECG with a time constant that is too short. Note the

[1]Circulation, Volume XXXV, March, 1967.

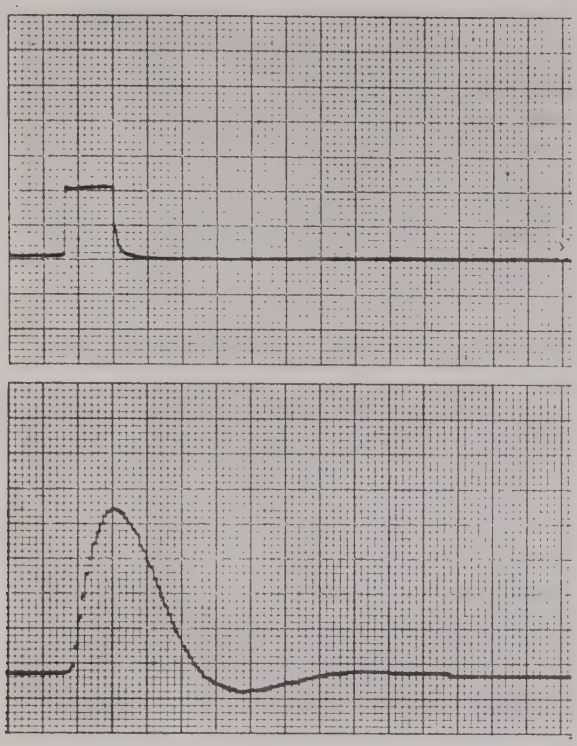


Figure 6. TEST Pulse and Defibrillator Waveform on Correctly Compensated ECG

droop and undershoot present on the TEST pulse, the increase in the undershoot of the defibrillator pulse and the reduction in pulse duration.

Therefore, to obtain the most accurate results, it is advisable to measure the time constant of the ECG being used. If the time constant is not 3.2 seconds, then the user should do one of the following: (1) obtain an ECG with a time constant of 3.2 seconds, or (2) adjust the compensating network to match the ECG being used. (Consult the factory for the proper procedure in this instance.)

8.2 To measure ECG time constant:

(a) Turn on ECG.

(b) Set ECG to "STD" position.

(c) Set speed to 25mm/sec.

(d) Run ECG.

(e) Press 1mv button.

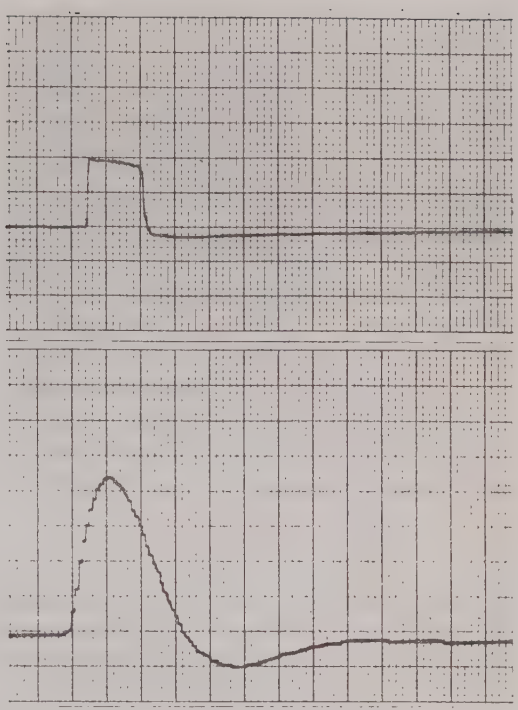


Figure 7. TEST Pulse and Defibrillator Waveform on Incorrectly Compensated ECG

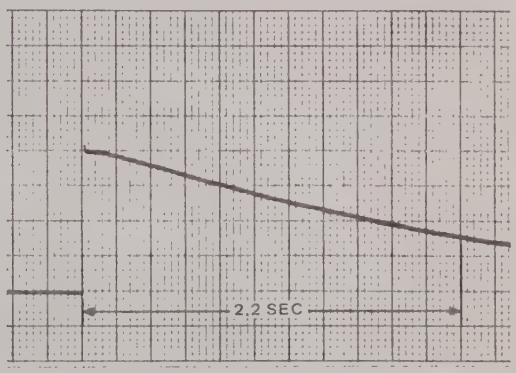


Figure 8. Measuring the ECG Time Constant

(f) Measure time for 1mv signal to decay to 36.8% of initial value. (See Figure 8.)

Each 5mm division = 0.2 sec. The measured time represents the ECG time constant. If it does not equal 3.2 seconds (±10%), the DA-2 compensation network should be modified to match.

8.3 Cardiac monitors generally have time constants that are much shorter than 3.2 seconds. When displaying or recording the output waveform from a cardiac monitor be sure that "monitor/diagnostic" switch is set to "diagnostic" position. Figure 9 shows a typical TEST 1KV pulse recorded from a cardiac monitor.

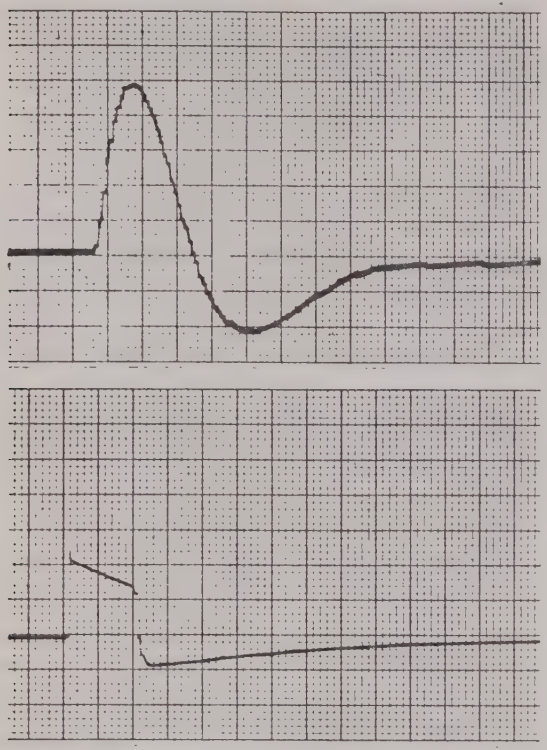


Figure 9. TEST Pulse and Defibrillator Waveform Recorded from Typical Cardiac Monitor

8.4 Recording from the Expanded Time High Level Output: No compensation is provided in the high-level output. Therefore, it is essential to use a DC-coupled recorder or oscilloscope to maintain the fidelity of the output waveform.

9.0 SYNCHRONIZER TEST

9.1 Set DEFIB/SYNC switch to SYNC TEST

9.2 Press READY button. A simulated R-wave of 1 millivolt amplitude at 60 beats per minute is now present at the Input Discs and at the LA output jack. A 1 volt R-wave is present at the EXPANDED TIME output jack.

9.3 If the defibrillator-under-test monitors through paddles:

(a) Charge defibrillator to desired level

(b) Apply paddles to input discs

(c) If necessary, adjust defibrillator SENSITIVITY control to assure synchonization.

(d) Press defibrillator discharge buttons

(e) After defibrillator discharges, the DA-2 display will read the delay, in milliseconds, between the simulated R-wave and the defibrillator discharge.

9.4 If the defibrillator-under-test requires a low-level input, connect patient leads to DA-2 LA, RA, and RL jacks. Perform procedure of paragraph 9.3.

9.5 If the defibrillator-under-test requires a high-level input, connect sync input to DA-2 EXPANDED TIME output jack. Perform procedure of paragraph 9.3.

10.0 SAFETY

10.1 Defibrillator with Grounded Paddles: The Model DA-2 Defibrillator Analyzer has been designed to insure operator safety under all normal conditions. A high-impedance differential input circuit permits applying the defibrillator's paddles interchangeably to the input discs. There is no need to distinguish which paddle is grounded since each input disc is isolated from ground by one million ohms. *No direct low-resistance path* exists between the input discs and the chassis or output terminals. In the event that a fault condition occurs; i.e., the DA-2 chassis becomes ungrounded, while testing a defibrillator which has a grounded paddle, the maximum current pulse that could flow from the DA-2 chassis to the operator will not exceed 3 to 4 milliamperes. According to Dalziel,[2] this amount of current is perceptible, but well below the current at which the subject can not let go.

Nevertheless, it is recommended that the DA-2 only be plugged into three-wire outlets that have been inspected for proper grounding. This precaution should be followed for *all* electrically-operated devices to prevent shock hazards from line-to-chassis faults.

.10.2 Handling Defibrillator Paddles: Defibrillator paddles, being a source of high voltage, must be handled carefully by the user. Always observe the following:

(a) Apply paddles **only** to the DA-2 input discs.

(b) **Avoid** making contact with any other parts of the DA-2.

[2]Dalziel, C.F...., "Electric Shock Hazard," I.E.E.E. Spectrum, February, 1972.

(c) **Do not allow** the defibrillator paddles to come in contact with the skin at any time.

(d) **Do not use** electrode paste or saline pads to make contact between the defibrillator paddles and the DA-2 input discs.

(e) Apply the paddles firmly to the input discs, holding one paddle in each hand.

(f) For those defibrillators that do not have paddle switches or foot switches, a second person must be present to push the defibrillator discharge button.

11.0 PRINCIPLES OF OPERATION

11.1 Energy Level Meter: A 50-ohm, non-inductive, high-power resistor is built into the DA-2, connected across the test discs. This resistor simulates the resistance of a patient undergoing defibrillation. The energy delivered to a resistor is computed by the following formula: $W = \int (V^2/R)\, dt$, where W = energy, V = voltage across resistor R, and $\int (—)\, dt$ represents the integral with respect to time. If we sample a portion of the voltage across the resistor, square it, then integrate the result for a time interval longer than the duration of the waveform, we will have an output signal whose level is directly proportional to the energy delivered to the load resistor.

The DA-2 contains an electronic squaring circuit and integrator to perform this operation. The resulting voltage level is fed to a "converter" which changes the voltage to a series of precisely-timed pulses which drive a digital counter and display. The display consists of three 7-segment LED's, capable of displaying 000 to 999. The maximum energy level measured by the circuitry is approximately 900 joules, because the integrator saturates somewhere above this level. The minimum measurable energy level is about 10 joules, because an input pulse of several hundred volts is required to trigger the logic circuits.

11.2 Time Expander: The time expander portion of the DA-2 contains a memory circuit which stores the defibrillator waveform so that it may be "read out" at a relatively slow rate, suitable for recording on an electrocardiograph. The defibrillator waveform is reduced in voltage amplitude by a factor of one thousand and fed to an analog-to-digital converter. There the waveform is converted to a digital format (a series of coded pulses), and stored in a digital memory circuit. After a predetermined time interval, the digital information is read out of the memory circuit into a digital-to-

analog converter, which changes the coded digital information into a time-varying analog voltage having the identical shape and amplitude as the attenuated defibrillator pulse, except that it is "stretched" in time by a factor of 200. A defibrillator pulse that is, for example, 4 milliseconds (thousandths of a second) in length, is converted to an output pulse 800 milliseconds in length. the expansion factor of 200 is chosen so that one millisecond of real time is expanded to 200 milliseconds, which exactly corresponds to the time between the heavy 5-millimeter divisions of standard ECG paper when the paper drive speed is 25mm/sec. Thus, each 5mm division represents 1 millisecond so the duration of the defibrillator pulse, in milliseconds, can easily be determined.

Note, that, because the defibrillator waveform has been "digitized," the DA-2 output is actually formed of many small discrete levels or "jumps" put together to form a continuous waveform. This may appear as a slight "staircase" or "sawtooth" effect on the output waveform, especially on ECG's that have good high-frequency response. This effect is normal and should not be interpreted as improper operation (See Figures 6, 7 and 9.)

Two time-expanded outputs are available. One is a high-level output whose scale factor is one volt out per 1000 volts in, for viewing on an oscilloscope or recording on a writer or recorder requiring a high-level input. The second output is a low-level output for direct connection to an ECG. The scale factor is one millivolt out per 1,000 volts in, and three terminals marked LA, RL, and RA are provided for connecting a patient cable. If the ECG is set to Lead 1, and gain is adjusted to one millivolt per 10mm, then each 1mm division will correspond to 100 volts and the defibrillator peak voltage can easily be measured.

A compensating network is contained in the low-level output current which compensates for the AC-coupling time constant of the ECG. The compensating network is matched to the time constant of 3.2 seconds, recommended for electrocardiographs by the American Heart Association, since most recently built ECG's use this value. However, other time constants can be compensated. Consult the factory if a different time constant is desired.

11.3 Synchronizer Test Circuit

The DA-2 contains a precision master clock oscillator which generates all the timing and counting signals. A 1kHz clock and a 1 beat per minute pulse are derived from

the master clock. The 1 BPM pulse is shaped and delivered to the DA-2 output jacks. It also gates the 1 kHz clock into a circuit which counts from 0 up to 999. If a defibrillator discharge is received, the counting circuit stops and displays the number it contains, which represents the synchronizer delay in milliseconds.

12. MAINTENANCE

The Bio-Design Model DA-2 Defibrillator Analyzer is designed to give long and reliable operation with a minimum of maintenance. Occasional cleaning is desirable. Specialized test equipment is required for alignment and calibration, so it is recommended that the DA-2 be returned to the factory when calibration is desired. A nominal charge will be made for this service.

12.1 Cleaning: Ocassionally wipe the control panel and all other surfaces with a slightly damp cloth, with special attention to the Energy Meter display filter. Do not use abrasive cleaners or steel wool on these surfaces.

To clean input discs use a mild cleaning powder, rubbing gently with a damp cloth or sponge. Be sure to dry all surfaces after cleaning.

12.2 To Remove DA-2 from Case: There is no need to open the DA-2 panel in the course of ordinary use and maintenance. If internal access should become necessary, follow directions below:

(a) Disconnect DA-2 line cord from AC outlet.

(b) Remove four screws located at each corner of DA-2 panel, carefully lift panel up and out of case.

WARNING

THE DA-2 SHOULD BE SERVICED BY QUALIFIED PERSONNEL.

SHOCK HAZARD

LINE VOLTAGE IS PRESENT IN THE DA-2. USE CAUTION WHEN DA-2 IS REMOVED FROM CASE AND PLUGGED INTO AC OUTLET.

ERRATA

Paragraph 11.3.
"1 beat per minute" should read
"60 beats per minute."